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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,791	02/27/2006	Yorimasa Suwa	1254-0305PUS1	6478

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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	**PAPER NUMBER**
1647	

NOTIFICATION DATE	DELIVERY MODE
01/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/569,791	SUWA ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 13-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/27/06, 7/5/06, 1/10/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 9-12 in the reply filed on 11/8/07 is acknowledged.

Claims 1-8 and 13-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/8/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 9 is directed to a screening method for an antidiabetic where the final step is detecting the interaction between the candidate substance and the protein of SEQ ID NO: 2 or a sequenced derived therefrom. However, detection of an interaction does not necessarily identify the compound as an antidiabetic. The claims do not require that any antidiabetic properties of any compound identified be determined. It is noted that piglitazone was already known and characterized as an antidiabetic. It's interaction with SEQ ID NO: 2 did not identify or characterize these properties.

The specification provides no example elucidating the role of SEQ ID NO: 2 in diabetes. The specification does not demonstrate that any novel compounds identified as interacting with SEQ ID NO: 2 have any antidiabetic properties. It is noted that thiazolidine compounds have uses in addition to applications in diabetes. For example, Miller et al. (U.S. Patent No. 7,307,093) discloses their uses in cancer and Gungor et al. (U.S. Patent No. 7,205,322) discloses additional pharmaceutical uses. As such, merely determining an interaction with SEQ ID NO: 2 would not have been sufficient to draw a conclusion as to any antidiabetic properties. The fact that a known antidiabetic agent bound to SEQ ID NO: 2 would not be sufficient evidence for one of ordinary skill in the art to assume that any agent that bound to SEQ ID NO: 2 would be an antidiabetic.

Part (b) of claim 9 is directed to a mutated protein. However, the specification does not specifically describe nor exemplify any mutated proteins within the scope of the claims that interacts with any antidiabetic compound. It is unclear what specific biological activity must be retained by the mutated protein. It is unclear what mutated proteins would retain those structural features necessary to identify a novel antidiabetic.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. In the instant application, there are no working examples, there is no specific guidance as to

mutated proteins of SEQ ID NO: 2, the prior art does not recognize SEQ ID NO: 2 as being involved in diabetes, and the claims are broad. It is not considered to be so predictable that any compound that interacted with SEQ ID NO: 2 or a mutated version thereof would possess antidiabetic properties. The claims are considered to require undue experimentation to practice.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is directed to a screening method for an antidiabetic where the final step is detecting the interaction between the candidate substance and the protein of SEQ ID NO: 2 or a sequenced derived therefrom. However, detection of an interaction does not necessarily identify the compound as an antidiabetic. These antidiabetic properties are not determined. The claim is confusing because the steps of the method do not correspond to the preamble of the method.

Claim 9, part (b), recites "interacting with the antidiabetic." This is confusing. It appears that what may have been intended was the "candidate substance to be screened" as the antidiabetic is the compound that is being screened for. Likewise in claim 10 it appears that "candidate substance to be screened is a thiazolidine derivative" was intended rather than the antidiabetic.

Claim 11 is confusing because it appears to identify a known antidiabetic compound that is already known to interact with SEQ ID NO: 2. The method of this claim is not screening or

further identifying any compound. This differs from claim 10 which is considered to be directed to identifying the class of compounds to screen.

Claim 12 lacks antecedent basis for "target protein" in claim 9. This claim is further confusing as SEQ ID NO: 2 already appears to meet the limitation of a γ-tubulin ring complex protein. If this limitation was directed to part (b) of claim 9, it is not known what modifications to SEQ ID NO: 2 would continue to meet the limitation of a γ-tubulin ring complex protein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/

Primary Examiner, Art Unit 1647

mpa